REMARKS/ARGUMENTS

I. STATUS OF THE CLAIMS

Upon entry of this amendment, claims 41, 43-44, 48, 51-52, 56, and 75-86 are pending in this application and are presented for examination.

Claims 1-40, 42, 45-47, 49-50, 53-55, and 57-74 have been canceled without prejudice.

Claims 41, 43-44, 48, 51-52, 56, and 75 have been amended. In particular, claim 41 has been amended to recite a purified or isolated nucleic acid molecule comprising a sequence selected from the group consisting of: (a) SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5; and (b) the complementary sequence of SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5. Support is found, for example, in Figures 6 and 8 and on page 8, lines 32-33 of the instant specification. Claims 43-44 and 48 have been amended to correct minor informalities. Claim 51 has been amended to recite an isolated host cell and to establish proper dependency from claim 48. Support is found, for example, on page 12, lines 23-27. Claim 52 has been amended to delete non-elected subject matter and to correct minor informalities. Claim 56 has been amended to establish dependency from claim 77 and to recite a diagnostic composition for diagnosing or assessing an individual's predisposition to develop adult-type hypolactasia. Support is found, for example, on page 16, lines 19-29. Claim 75 has been amended to establish dependency from claim 77 and to correct a minor informality.

Claims 76-86 have been newly added. Support for new claims 76-82 is found, for example, in Figures 6 and 8; from page 8, line 15 to page 9, line 17; from page 11, line 23 to page 12, line 7; and on page 30, lines 15-19. Support for new claim 83 is found, for example, in original claim 1; on page 5, lines 1-16; and in Figures 6 and 8. Support for new claims 84-85 is found, for example, in original claim 10; on page 5, lines 1-16; and on page 11, lines 19-24. Support for new claim 86 is found, for example, in original claim 38 and on page 22, lines 17-20.

No new matter has been introduced with the foregoing amendments. Reconsideration is respectfully requested.

II. REJOINDER OF SPECIES

In the Office Action, the Examiner has stated that the restriction between SEQ ID NO:1 and SEQ ID NO:3 has been changed to a species election (*see,* Office Action at page 2). As the remarks herein put the case in condition for allowance, Applicants have rejoined the species of SEQ ID NO:3.

III. PRIORITY

The Examiner has requested copies of the priority documents, namely EP 01119377.8, filed August 10, 2001, and EP 01119528.6, filed August 14, 2001. In compliance with this request, Applicants submit herewith copies of the priority documents. As these documents are in the English language, no translation is necessary.

IV. CLAIM OBJECTION

Claims 41-42 were objected to as allegedly containing references to figures. Applicants have amended claim 41 to delete any reference to figures. Applicants have also canceled claim 42 without prejudice.

Claims 51-52 were objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. As noted above, Applicants have amended claim 51 to establish proper dependency from claim 48.

In view of the foregoing, Applicants respectfully request that the objection to the claims be withdrawn.

V. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 41, 43-46, 48-52, 56, and 75 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

As noted above, claim 41 has been amended to recite a purified or isolated nucleic acid molecule comprising a sequence selected from the group consisting of: (a) SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5; and (b) the complementary sequence of SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5. Claim 51 has been amended to establish proper dependency from claim 48.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, second paragraph.

VI. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

A. Enablement

Claims 51-52 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

The Examiner alleges that the specification, while being enabling for an isolated non-human host cell, does not reasonably provide enablement for any host organism transformed with a vector comprising a nucleic acid molecule of the present invention (*see,* Office Action at page 6).

As noted above, claim 51 has been amended to recite an *isolated host cell.* Applicants assert that the specification as filed provides numerous examples of isolated host cells that can be transformed with a vector comprising a nucleic acid molecule of the present invention, including *E. coli* cells, *S. cerevisiae* cells, *Pichia pastoris* cells, *Aspergillus* cells, *Spodoptera frugiperda* cells, and CaCo2 cells from a human colorectal adenocarcinoma cell line (*see, e.g.,* page 12, lines 23-27).

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

B. Written Description

Claims 41, 43-46, 48-52, 56, and 75 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking sufficient written description. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

The Examiner alleges that Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus (*see,* Office Action at page 12).

As noted above, claim 41 has been amended to recite a purified or isolated nucleic acid molecule comprising a sequence selected from the group consisting of: (a) SEQ ID NO:1,

SEQ ID NO:3, or SEQ ID NO:5; and (b) the complementary sequence of SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5. Claim 56 has been amended to recite a diagnostic composition for diagnosing or assessing an individual's predisposition to develop adult-type hypolactasia comprising a nucleic acid molecule consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof. Similarly, claim 75 has been amended to recite a kit comprising a nucleic acid molecule consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof.

As set forth in MPEP § 2163(II)(A)(3)(a), an adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). For biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. *See*, MPEP § 2163(II)(A)(3)(a).

Contrary to the Examiner's allegation, the specification clearly demonstrates to one of skill in the art that the present inventors were in full possession of the claimed invention at the time of filing. In particular, the specification provides the complete sequence of intron 13 of the MCM6 gene (*i.e.*, wild-type sequence, Figure 6; "C/T_{-13910}" variant sequence, Figure 8) from which nucleic acid molecules consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof can be derived.

In addition, Example 3 on pages 28-30 of the specification provides the sequence and length of a variety of oligonucleotide primers consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof. For example, the specification at page 30, lines 15-19 provides PCR primers for amplifying the "C/T_{-13910}" variant in intron 13 of the MCM6 gene and a sequencing primer for detecting the variant. The forward PCR primer (SEQ ID NO:8) is 23 nucleotides in length and consists of nucleotides 7-29 of SEQ ID NO:3 or SEQ ID NO:5. The reverse PCR primer (SEQ ID NO:9) is 23 nucleotides in length and consists of nucleotides 415-437 of a sequence complementary to

SEQ ID NO:3 or SEQ ID NO:5. The sequencing primer (SEQ ID NO:10) is 24 nucleotides in length and consists of nucleotides 300-323 of SEQ ID NO:3 or SEQ ID NO:5. Accordingly, the specification is more than adequate to demonstrate to one of skill in the art that Applicants had possession of the presently claimed polynucleotide sequences at the time the application was filed.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

VII. REJECTION UNDER 35 U.S.C. § 102

For a rejection of claims under § 102 to be properly founded, the Examiner must establish that a single prior art reference either expressly or inherently discloses each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Verdegaal Bros. V. Union Oil Co. Of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991), the Federal Circuit held that:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Id.* at 1010.

Anticipation can be found, therefore, only when a cited reference discloses all of the elements, features, or limitations of the presently claimed invention.

A. Rejection under 35 U.S.C. § 102(e)

Claims 41, 43-46, 48, 51-52, 56, and 75 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Ye *et al.* (U.S. Patent No. 6,492,155). To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

The Examiner alleges that a portion of SEQ ID NO:3 taught by Ye *et al.* corresponds to the nucleic acid molecule set forth in part (c) of claim 41 (*see,* Office Action at

page 13). In response, Applicants assert that Ye *et al.* fails to teach all the elements of the claimed invention.

As noted above, claim 41 has been amended to recite a purified or isolated nucleic acid molecule comprising a sequence selected from the group consisting of: (a) SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5; and (b) the complementary sequence of SEQ ID NO:1, SEQ ID NO:3, or SEQ ID NO:5. As a result, part (c) has been deleted from the claim. With regard to claim 41 as amended, Applicants assert that Ye *et al.* fails to teach or suggest the presently claimed nucleic acid molecules comprising SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof. As such, Ye *et al.* does not anticipate the presently claimed nucleic acid molecules because each and every element as set forth in the amended claims is not found in the reference. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 102(e).

B. Rejection under 35 U.S.C. § 102(b)

Claims 49-50 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Brennan (U.S. Patent No. 5,474,796). As noted above, Applicants have canceled claims 49-50 without prejudice, thereby rendering this rejection moot. Thus, Applicants respectfully request that this rejection be withdrawn.

VIII. REJECTION UNDER 35 U.S.C. § 103(a)

Claim 75 was rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ye *et al.* in view of Ahern (*The Scientist*, 9:20 (1995)). To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. *See also, In re Rouffet,* 47 USPQ2d 1453 (Fed. Cir. 1998).

Recently, the U.S. Supreme Court affirmed *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966) and indicated that the idea underlying the teaching, suggestion, or motivation (TSM) test is not inconsistent with the *Graham* analysis. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739-1741 (2007). In fact, the Court recognized that the TSM test provides a helpful insight in determining whether the claimed subject matter is obvious over a combination of prior art elements. *KSR*, 127 S.Ct. at 1741. *See also*, page 1 of the USPTO KSR Memorandum dated May 3, 2007. The Court also noted that the analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR*, 127 S.Ct. at 1740-1741. *See also*, page 2 of the USPTO KSR Memorandum.

The Examiner alleges that it would have been obvious to one of ordinary skill in the art to package the nucleic acid of Ye *et al.* in a kit taught by Ahern (*see,* Office Action at page 16). In response, Applicants assert that the presently claimed invention is not obvious in view of the cited art for at least the following reason: the combination of references does not teach or suggest all the elements of the presently claimed invention.

In particular, none of these references teaches or suggests the presently claimed kits comprising a nucleic acid molecule consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof. Rather, Ye *et al.* discloses amino acid and nucleic acid sequences of human kinases that are related to the serine/threonine protein kinase subfamily, and not the nucleic acid molecules recited in the presently claimed kits. Likewise, Ahern provides examples of premade biochemical reagents and kits without supplying any teaching or suggestion whatsoever of the nucleic acid molecules recited in the presently claimed kits. As a result, these references simply fail to contemplate kits comprising a nucleic acid molecule consisting of a sequence of at least 14 consecutive nucleotides of SEQ ID NO:3, SEQ ID NO:5, or a complementary sequence thereof. Therefore, the combination of references does not disclose or suggest all the elements of the presently claimed invention.

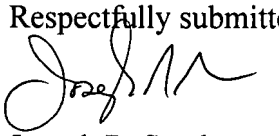
In view of the foregoing, the combined disclosures of Ye *et al.* and Ahern do not render the claimed kits obvious. Accordingly, the Examiner is respectfully requested to withdraw the present rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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